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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/510,560	02/22/2000	Kenneth Iain Cumming	00.1090.US	3011

7590 05/18/2005

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EXAMINER	
CELSA, BENNETT M	
ART UNIT	**PAPER NUMBER**
1639	

DATE MAILED: 05/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/510,560	CUMMING ET AL.	
	Examiner	Art Unit	
	Bennett Celsa	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-39,41,42,47 and 49-86* is/are pending in the application.

4a) Of the above claim(s) *8,9,59,60 and 67-86* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-7,10-39,41,42,47,49-58 and 61-66* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Claims 1, 3-39, 41-42, 47 and 49-86 are currently pending.

Claims 8-9, 59-60 and 67-86 are withdrawn from consideration as being directed to a nonelected invention.

Claims 1, 3-7, 10-39, 41-42, 47, 49-58, and 61-66 are under consideration.

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

1. Applicant's election of:

a. low molecular weight heparin (as the drug);

b. sodium caprate (as the salt of a medium chain fatty acid); and

c sodium caprate and halide of caprate (as a single combination of a fatty acid salt and fatty acid acyl derivative); .

in the reply filed on 4/21/05 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claims 8-9, 59-60 and 67-86 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

Claim Rejections - 35 USC § 102

3. Claims 1, 3-7, 10-39, 47, 49-58, and 61-66 are rejected under 35 U.S.C. 102(a,b) as being anticipated, or in the alternative as prima facie obvious over Watts et al. WO 97/05903 (2/97).

Claim 1 (and claims dependent thereon) is drawn to:

A solid oral dosage form comprising :

i. a drug; and

ii. a salt of a medium chain (6-20 carbons) fatty acid (e.g. as an enhancer: preferably capric acid (C10) and its sodium salt: sodium caprate) separately or in combination with fatty acid derivatives.

Although the composition requires that "each of said constituents and any other constituent comprising the composition is a solid at room temperature" this limitation is not afforded patentable weight since it refers to the physical state of the intermediates and the use of the intermediates to make the final product. In other word, this limitation defines the ultimate product by its process of manufacture (e.g. dry blending). A product-by-process claim is treated by the PTO as product.

Watts el al. disclose a drug delivery composition for colonic delivery comprising a drug (e.g. polypeptide and polysaccharide including heparin and low molecular weight heparin: see e.g. page 8), and an absorption promoter (p 24, claim 1). More specifically, Watts el al teach that the absorption promoter comprises a fatty acid or a salt thereof, where the fatty acid has between 6 and 16 carbon atoms, for example capric acid or its (sodium) salt (e.g. se pages 5, 24, claims 1 and 3) which can be used alone or in

admixture with a fatty acid derivative (e.g. mono/diglycerides: see pages 5-7) to obtain synergy. Watts el a/. further teach that the drug can be chosen from insulin, calcitonin, LHRH, buserelin, goserelin, vasopressin, heparin, and more (p 8, 11-12, and p 24, claim 6). Lastly, Watts el a/. teach that the composition is formulated in a capsule (e.g. hard/soft gelatin), tablet, or pellet which is comprised of or coated with a material which is dissolved by the conditions found in the intestines e.g. "rate-controlling" (e.g. sustained release), such as a cellulose ester, HPMC (e.g. see page 9, line14-18) or a methacrylic acid polymer (p 1012, 25, claims 8, and 12-14) for in vivo therapeutic administration to a patient (e.g. see pages 14-15).

4. Claims 1, 3-6, 10-13, 26-28, 39, 52-57 and 61-66 are rejected under 35 U.S.C. 102(a,b) as being anticipated by Inamori et al., Proc. Int's Symp. Control. Rel. Bioact. Mat. 24th (1997) pages 283-284.

Claim 1 (and claims dependent thereon) is drawn to:

A solid oral dosage form comprising :

i. a drug; and

ii. a salt of a medium chain (6-20 carbons) fatty acid (e.g. as an enhancer: preferably capric acid (C10) and its sodium salt: sodium caprate) separately or in combination with fatty acid derivatives.

Although the composition requires that "each of said constituents and any other constituent comprising the composition is a solid at room temperature" this limitation is not afforded patentable weight since it refers to the physical state of the intermediates

and the use of the intermediates to make the final product. In other word, this limitation defines the ultimate product by its process of manufacture (e.g. dry blending). A product-by-process claim is treated by the PTO as product.

Inamori et al. Teach that intestinal absorption of a drug (e.g. an anti-thrombin drug Argatroban) is enhanced by solid oral dosage formulations (tablet/enteric-coated & fast release granules) comprising medium chain fatty acid sodium salts (e.g. capric (C10) acid sodium salt) as an absorption enhancer for patient administration (e.g. dog/human). The drug and enhancer may be present in solid form in physical admixture (e.g. at room temperature).

5. Claims 1, 3, 6, 10- 14,16-28,33-39, 41-42, 47, 52-54,57 and 61-66 are rejected under 35 U.S.C. 102(a,b) as being anticipated by Jang WO 84/04674 (12/84).

Claim 1 (and claims dependent thereon) is drawn to:

A solid oral dosage form comprising :

i. a drug; and

ii. a salt of a medium chain (6-20 carbons) fatty acid (e.g. as an enhancer: preferably capric acid (C10) and its sodium salt: sodium caprate) separately or in combination with fatty acid derivatives.

Although the composition requires that "each of said constituents and any other constituent comprising the composition is a solid at room temperature" this limitation is not afforded patentable weight since it refers to the physical state of the intermediates and the use of the intermediates to make the final product. In other word, this limitation

defines the ultimate product by its process of manufacture (e.g. dry blending). A product-by-process claim is treated by the PTO as product.

Jang teaches solid oral dosage forms (e.g. controlled-release dosage forms) formed by dry, direct particle compression (to form multiparticlulates and compressed tablets) of:

i. a drug

ii. organic salts of C11-C28 fatty acids alone or blended with C12-C28 fatty acids and/or C12-C28 fatty acid derivatives (e.g. monalcohols/amides/glycerides and

ii. carbohydrate polymer (e.g. ethyl/propyl celluloses) ;

(see E.g. See abstract ; .pages 4, 6-9; examples; and claims)

which components are solid at room temperature.

Claim Rejections - 35 USC § 103

6. Claims 1, 3-7, 10-39, 41-42, 47, 49-58, and 61-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Watts et al. WO 97/05903 (2/97). In view of Jang WO 84/04674 (12/84) and/or Inamori et al., Proc. Int's Symp. Control. Rel. Bioact. Mat. 24th (1997) pages 283-284.

Claim 1 (and claims dependent thereon) is drawn to:

A solid oral dosage form comprising :

i. a drug; and

ii. a salt of a medium chain (6-20 carbons) fatty acid (e.g. as an enhancer: preferably capric acid (C10) and its sodium salt: sodium caprate) separately or in combination with fatty acid derivatives.

Although the composition requires that "each of said constituents and any other constituent comprising the composition is a solid at room temperature" this limitation is not afforded patentable weight since it refers to the physical state of the intermediates and the use of the intermediates to make the final product. In other word, this limitation defines the ultimate product by its process of manufacture (e.g. dry blending). A product-by-process claim is treated by the PTO as product.

Present claim 41 (and dependent claim 42) is drawn to a method of making a solid oral dosage form comprising a blend of room temperature solids of:

i. a drug;

ii. a medium chain (6-20) fatty acid or salt or derivative thereof; and

iii. optional components.

Which is formed into a solid oral dosage form by

i. direct compression of the blend (e.g. to form tablets); or

ii. granulating the blend to form a granulate for incorporation into said dosage form.

Watts el al. disclose a drug delivery composition for colonic delivery comprising a drug (e.g. polypeptide and polysaccharide including heparin and low molecular weight heparin: see e.g. page 8), and an absorption promoter (p 24, claim 1). More specifically, Watts el al teach that the absorption promoter comprises a fatty acid or a salt thereof, where the fatty acid has between 6 and 16 carbon atoms, for example capric acid or its (sodium) salt (e.g. se pages 5, 24, claims 1 and 3) which can be used alone or in admixture with a fatty acid derivative (e.g. mono/diglycerides: see pages 5-7) to obtain synergy. Watts el a/. further teach that the drug can be chosen from insulin, calcitonin,

LHRH, buserelin, goserelin, vasopressin, heparin, and more (p 8, 11-12, and p 24, claim 6). Lastly, Watts el a/. teach that the composition is formulated in a capsule (e.g. hard/soft gelatin), tablet, or pellet which is comprised of or coated with a material which is dissolved by the conditions found in the intestines e.g. "rate-controlling" (e.g. sustained release), such as a cellulose ester, HPMC (e.g. see page 9, line14-18) or a methacrylic acid polymer (p 1012, 25, claims 8, and 12-14) for in vivo therapeutic administration to a patient (e.g. see pages 14-15).

The Watts reference differs from the present invention by failing to teach dry direct compression of its composition components to form tablet or granulates for capsule incorporation (present claims 41 and 42, respectively).

However, the Jang or Inamori reference teachings taken separately or in combination provide motivation to one of ordinary skill in the art to formulate the Watt reference solid dosage oral formulations (e.g. tablets/capsules/pellets) by dry compression to form tablet or granulates for capsule incorporation since these references demonstrate that fatty acids and/or their derivatives achieve favorable intestinal drug absorption upon formation of the oral dosage form utilizing dry component blending.

For example, Jang teaches solid oral dosage forms (e.g. controlled-release dosage forms) formed by dry, direct particle compression (to form multiparticlulates and compressed tablets) of:

i. a drug

ii. organic salts of C11-C28 fatty acids alone or blended with C12-C28 fatty acids and/or C12-C28 fatty acid derivatives (e.g. monalcohols/amides/glycerides and

ii. carbohydrate polymer (e.g. ethyl/propyl celluloses) ;

(see E.g. See abstract ; .pages 4, 6-9; examples; and claims)

which components are solid (e.g. particles) at room temperature.

Similarly, Inamori et al. Teach that intestinal absorption of a drug (e.g. an anti-thrombin drug Argatroban) is enhanced by solid oral dosage formulation (tablet/enteric-coated & fast release granules) of medium chain fatty acid sodium salts (e.g. capric (C10) acid sodium salt) as an absorption enhancer for patient administration (e.g. dog/human). The drug and enhancer is preferably present in solid form in physical admixture (e.g. at room temperature).

Accordingly, it would have been prima facie obvious to one of ordinary skill in the art at the time of applicant's invention to formulate the Watt's reference oral dosage formulations using dry solid compression of its ingredients in light of the favorable absorption drug enhancement realized by the Jang and/or Inamori references.

7. Claims 1, 3-7, 10-39, 41-42, 47, 49-58, and 61-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Watts et al. WO 97/05903 (2/97) in view of Jang and/or Inamori as applied to claims 1, 3-7, 10-39, 41-42, 47, 49-58, and 61-66 above, and further in view of Briskin et al. WO 95/22319 (8/95).

The combined teaching of the the Watts reference taken in view of Jang and/or Inamori in the obviousness rejection described above is hereby incorporated by reference in its entirety.

The Watts reference teaching (alone or in combination with Jang and/or Inamori) differ from the elected invention by failing to teach a halogen (e.g. hydbromide/ hydrochloride) salt of sodium caprate as the enhancer.

However, the Watts reference alone (or combined with Jang and/or Inamori) clearly teach the use of any C6-C16 fatty acid or salt thereof but preferably a sodium salt particularly sodium caprate.

In this regard, pharmaceutically acceptable salts e.g. carboxylate salts are known to encompass functionally equivalent cationic alkali/alkaline earth metals such as sodium as well as halogen salts (e.g hydrobromide/hydrochloride). See e.g. Briskin at page 3, especially lines 3-25).

Accordingly, one of ordinary skill in the art would have been motivated to select a different fatty acid salt other than sodium (e.g. for sodium caprate) such as a halogen salt with a reasonable expectation of retaining the intestinal enhancement qualities of the Watt reference oral dosage formulations.

Thus, it would have been prima facie obvious to one of ordinary skill in the art at the time of applicant's invention to formulate a pharmaceutically acceptable acid halide salt of the medium chain fatty acids (e.g. sodium caprate) disclosed in the Watts reference in order to obtain a functionally equivalent enhancers for use in formulating solid oral dosage formulations for drug delivery in accordance with the Watts reference teaching method taken alone or as modified by the Jang and/or Inamori reference teaching(s).

8. Claims 1, 3-7, 10-13, 26-28, 39, 52-58 and 61-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Inamori et al., Proc. Int's Symp. Control. Rel. Bioact. Mat. 24th (1997) pages 283-284 in view of Einarsson US Pat. No. 5,714,477 (2/98: filed 12/95) and/or Watts.

Claim 1 (and claims dependent thereon) is drawn to:

A solid oral dosage form comprising :

i. a drug; and

ii. a salt of a medium chain (6-20 carbons) fatty acid (e.g. as an enhancer: preferably capric acid (C10) and its sodium salt: sodium caprate) separately or in combination with fatty acid derivatives.

Although the composition requires that "each of said constituents and any other constituent comprising the composition is a solid at room temperature" this limitation is not afforded patentable weight since it refers to the physical state of the intermediates and the use of the intermediates to make the final product. In other word, this limitation

defines the ultimate product by its process of manufacture (e.g. dry blending). A product-by-process claim is treated by the PTO as product.

Inamori et al. Teach that intestinal absorption of a drug (e.g. an anti-thrombin drug Argatroban) is enhanced by solid oral dosage formulation (tablet/enteric-coated & fast release granules) of medium chain fatty acid sodium salts (e.g. capric (C10) acid sodium salt) as an absorption enhancer for patient administration (e.g. dog/human). The drug and enhancer may be present in solid form in physical admixture (e.g. at room temperature).

The Inamori et al. Reference teaching differs from the presently claimed invention by failing to teach enhancing absorption of low molecular weight heparin (e.g. claims 7 and 58) using medium chain fatty acids and/or salts (e.g. capric (C10) acid sodium salt) .

However, Einarsson teach that the formation of solid oral dosage formulations of heparin and its low molecular fragments would be beneficial (e.g. as an alternative to injection with poor absorption: see e.g. col.1, especially lines 35-40) and further teach the use of medium chain (C6-18: especially caprylate and/or caprate) fatty acid derivatives (e.g. glycerides) for making oral dosage formulations. See e.g. col. 3, examples and patent claims.

Similarly, Watts el al. disclose a drug delivery composition for colonic delivery comprising a drug (e.g. polypeptide and polysaccharide *including heparin and low molecular weight heparin*: see e.g. page 8), and an absorption promoter (p 24, claim 1) the promoter comprising a fatty acid or a salt thereof, where the fatty acid has between

6 and 16 carbon atoms, for example capric acid or its (sodium) salt (e.g. se pages 5, 24, claims 1 and 3) which can be used alone or in admixture with a fatty acid derivative (e.g. mono/diglycerides: see pages 5-7) to obtain synergy.

Accordingly, one of ordinary skill in the art would have been motivated to make solid oral dosage formulations e.g. tablets/enteric-coated and fast release) comprising medium chain fatty acids and/or salts in accordance with the Immari method utilizing heparin and/or its low mw fragments in view of the Einarsson reference teaching that solid oral dosage formulations of heparin or its low mw fragments are desirable and achievable by using medium chain fatty acids (e.g. caprylate/caprate) and derivatives (e.g. glycerides) and/or in view of the Watts reference teaching of making solid oral dosage formulations comprising medium chain fatty acids and their derivatives (e.g. salts/glycerides) for heparin/low mw heparin administration.

Thus, it would have been prima facie obvious to one of ordinary skill in the art at the time of applicant's invention to utilize heparin and/or its fragments as the drug in the Imamori reference method of making solid oral dosage formulations with a reasonable expectation of achieving favorable intestinal drug absorption.

9. Claims 1, 3, 6, 7, 10-14,16-28,33-39, 41-42, 47, 52-54,57-58 and 61-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jang WO 84/04674 (12/84) in view of Einarsson US Pat. No. 5,714,477 (2/98: filed 12/95) and/or Watts.

Claim 1 (and claims dependent thereon) is drawn to:

A solid oral dosage form comprising :

i. a drug; and

ii. a salt of a medium chain (6-20 carbons) fatty acid (e.g. as an enhancer: preferably capric acid (C10) and its sodium salt: sodium caprate) separately or in combination with fatty acid derivatives.

Although the composition requires that "each of said constituents and any other constituent comprising the composition is a solid at room temperature" this limitation is not afforded patentable weight since it refers to the physical state of the intermediates and the use of the intermediates to make the final product. In other word, this limitation defines the ultimate product by its process of manufacture (e.g. dry blending). A product-by-process claim is treated by the PTO as product.

Jang teaches solid oral dosage forms (e.g. controlled-release dosage forms) formed by dry, direct particle compression (to form multiparticlulates and compressed tablets) of:

i. a drug

ii. organic salts of C11-C28 fatty acids alone or blended with C12-C28 fatty acids and/or C12-C28 fatty acid derivatives (e.g. monalcohols/amides/glycerides and

ii. carbohydrate polymer (e.g. ethyl/propyl celluloses) ;

(see E.g. See abstract ; .pages 4, 6-9; examples; and claims)

Which components are solid at room temperature.

The Jang reference teaching differs from the presently claimed invention by failing to teach enhancing absorption of low molecular weight heparin (e.g. claims 7 and 58) using medium chain fatty acids and/or salts (e.g. capric (C10) acid sodium salt) .

However, Einarsson teach that the formation of solid oral dosage formulations of heparin and its low molecular fragments would be beneficial (e.g. as an alternative to injection with poor absorption: see e.g. col.1, especially lines 35-40) and further teach the use of medium chain (6-8: especially caprylate and/or caprate) fatty acid derivatives (e.g. glycerides). See e.g. col. 3, examples and patent claims.

Similarly, Watts el al. disclose a drug delivery composition for colonic delivery comprising a drug (e.g. polypeptide and polysaccharide *including heparin and low molecular weight heparin*: see e.g. page 8), and an absorption promoter (p 24, claim 1). More specifically, Watts el al teach that the absorption promoter comprises a fatty acid or a salt thereof, where the fatty acid has between 6 and 16 carbon atoms, for example capric acid or its (sodium) salt (e.g. se pages 5, 24, claims 1 and 3) which can be used alone or in admixture with a fatty acid derivative (e.g. mono/diglycerides: see pages 5-7) to obtain synergy.

Accordingly, one of ordinary skill in the art would have been motivated to make solid oral dosage formulations e.g. tablets/enteric-coated and fast release) comprising medium chain fatty acids and/or salts in accordance with the Jang method utilizing heparin and/or its low mw fragments in light of the Einarsson reference teaching that

solid oral dosage formulations of heparin or its low mw fragments are desirable and achievable using medium chain fatty acids (e.g. caprylate/caprate) and derivatives (e.g. glycerides) and/or in view of the Watts reference teaching of making solid oral dosage formulations comprising medium chain fatty acids and their derivatives (e.g. salts/glycerides) for heparin/low mw heparin administration. .

Thus, it would have been prima facie obvious to one of ordinary skill in the art at the time of applicant's invention to utilize heparin and/or its fragments as the drug in the Jang reference method of making solid oral dosage formulations with a reasonable expectation of achieving favorable intestinal drug absorption.

Cumulative Prior Art:

1. Lin US Pat. No. 5,977,175 (11/99: filed 5/95) teaches solid oral dosage forms (e.g. tablets/troches/powders/granules/capsules: delayed/controlled/sustained release formulations) comprising C4-C24 fatty acids (e.g. capric/caprylic) and pharmacologically active agents. See patent claims.

Future Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bennett Celsa whose telephone number is 571-272-0807. The examiner can normally be reached on 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bennett Celsa
Primary Examiner
Art Unit 1639

BC
May 12, 2005